

REMARKS

As a preliminary note Applicants request acknowledgment of the claim of priority made in the Declaration and the Preliminary Amendment.

Applicants respectfully request entry of the amendments hereinabove, reconsideration of the Office Action mailed on November 20, 2002 and allowance of the claims.

Applicants wish to thank Examiner San-ming Hui for acknowledging the receipt of the Information Disclosure Statement submitted October 10, 2001. It is requested that the references listed on that previously submitted form PTO-FB-A820 be included in the "References Cited" portion of any patent issuing on this application (M.P.E.P. 1302.12).

Claims 31-35 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The rejection states that the term "including" is improperly applied in claims 33-35. The rejection also states that the term "beneficial" is subjective and has not been delineated. The rejection states that claims 32, 33 and 35 appear to define the same composition.

Applicants traverse (in part) the rejection of claims 31-35 under 35 U.S.C. 112, second paragraph in part.

Applicants have canceled claim 35 and amended claims 33 and 34 to recite comprising instead of "including". Applicants submit that the amended phrase is fully supported. Applicant further submits that the literal basis for such amendment is not required to be found in the specification (the claim phrase need not be "*in haec verba*" in the specification *In Re Wright* 9 U.S.P.Q.2d 1649, 1651 (Fed. Cir. 1989); *Crowne Operations, Int'l, Inc. v. Solutia, Inc.* 289 F.3d 1367, 1376 (Fed. Cir. 2002).

Applicants have cancelled claims 32 and 35 to remove any perceived redundancy.

Applicants strongly traverse the remaining ground of rejection made pursuant to 35 U.S.C. §112, second paragraph, that the use of the term "beneficial" in claim

31 as an adjective to modify "therapeutic response" is indefinite and submit that the term beneficial as used is definite.

"Thus, the first sentence of the second paragraph of 35 U.S.C. §112 is essentially a requirement for precision and definiteness of claim language. If the scope of subject matter embraced by a claim is clear, and if the Applicant has not otherwise indicated that he intends that claim to be of a different scope, then the claim does particularly point and distinctly claim the subject matter which the Applicant regards as his invention." In Re Borkowski, 164 U.S.P.Q. 642, at 645-646 (C.C.P.A. 1970).

It is clear from the above-cited language of Borkowski, that the second paragraph of section 112 contains two requirements.

The first requirement calls for precision and definiteness. In other words, one skilled in the art must be able to tell with a reasonable degree of certainty whether his or her conduct is within or outside the scope of the claim. Simply stated, the claims must not be "vague or indefinite" and must clearly set out the boundaries of the subject matter for which protection is granted by the patent.

Applicants submit that in accordance with In Re Borkowski the use of the term beneficial as an adjective to modify "therapeutic response" is definite.

The second requirement is that the claims must be directed to the subject matter that the Applicant regards as his or her invention. This means not only that an Applicant may claim whatever he or she regards as his or her invention, but also that an Applicant may not claim subject matter that he or she does not regard as his or her invention.

This requirement is simply not relevant to the current set of facts.

In summary, a claim that is understandable to one skilled in the art and that defines subject matter that Applicant regards as the invention meets the requirements of 35 U.S.C. §112, second paragraph. Stated another way, all that is required by the second paragraph of section 112 is that the claims set out and circumscribe a particular area that the Applicant regards as the invention with a reasonable degree of precision and particularity.

Applicants submit that as such they are in compliance with 35 U.S.C. §112, second paragraph.

Claims 1-3, 14-20, and 24-37 are rejected under 35 U.S.C. 102(e) as being anticipated by Gonzalez. The rejection refers to p. 24 [0497] and [0498]. The office action also notes that the claims are examined to the extent they read on the elected Y is a het ring.

Applicants submit that Gonzalez does not meet the requirements of 35 U.S.C. 102(e) since Gonzalez was not published under section 122 (b) before the instant invention by Applicants. Specifically, Gonzalez was filed on November 15, 2001 (while it does claim priority as a continuation-in-part to earlier filed U.S. applications; the relevant sections [0497] and [0498] are not included in the parent applications). The instant application was filed on June 28, 2001, which is prior to November 15, 2001. Accordingly, Gonzalez is unavailable as a 102(e) reference since it is a later filed application. In addition, the instant application claims priority to, for example, an earlier U.S. provisional application 60/219,100 filed on July 18, 2000 which includes disclosure of the [0497] and [0498] compounds of Gonzalez.

Enclosed is a Supplemental Information Disclosure Statement.

Attached hereto is a "Version with Markings to Show Changes Made."

Please charge any additional fees which may be required, or credit any overpayment, to Deposit Account No. 16-1445. Two copies of this sheet are enclosed.

Respectfully submitted,

Date: 4/10/2003



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VERSION WITH MARKINGS TO SHOW CHANGES MADE

IN THE CLAIMS



Please Cancel Claim 32.

Please amend claim 33 as follows:

- 33 (Amended) A pharmaceutical formulation ~~including~~ comprising a compound as defined in claim 2 together with a pharmaceutically acceptable excipient.

Please amend claim 34 as follows:

- 34 (Amended) A method for the treatment or prophylaxis of female sexual dysfunction ~~including~~ comprising administering to the patient a therapeutically effective amount of a compound as defined in claim 2.

Please Cancel Claim 35.